UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

B.F., a minor, BETH FORBES, individually and as next friend of B.F., and THOMAS FORBES, individually and as next friend of B.F.,	)	No. 4:12-CV-1760 CAS
Plaintiffs,	)	
v.	)	
ABBOTT LABORATORIES INC., et al.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This diversity matter is before the Court on defendant Abbott Laboratories Inc.'s ("Abbott") (1) motion to exclude the testimony of plaintiffs' expert witness Jack Land, M.D., and (2) motion to exclude certain opinion testimony of plaintiffs' expert witness Godfrey P. Oakley, Jr., M.D. pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Plaintiffs oppose the motions. Although Abbott has requested oral argument on the motions, the Court finds it can make a proper Daubert analysis without the need for oral argument. The parties have submitted a voluminous evidentiary record including exhibits and testimony.

For the following reasons, Abbott's motion to exclude plaintiffs' expert Dr. Land will be granted in part and denied in part. Abbott's motion to exclude certain opinion testimony of Dr. Oakley will be granted.

I. Background

In this products liability action, plaintiffs Thomas and Beth Forbes and their minor son B.F. ("plaintiffs") assert claims against Abbott arising out of injuries resulting from B.F.'s exposure *in utero* to the medicine Depakote. Beth Forbes began taking Depakote two years before B.F.'s birth to treat her bipolar disorder. Plaintiffs allege B.F. sustained serious and permanent injures and damages as a result of his mother's ingestion of Depakote during pregnancy, specifically that B.F. was diagnosed with spina bifida.

Plaintiffs brought this action against Abbott in seven counts, only two of which remain: Strict Liability—Failure to Warn (Count I) and Negligence—Failure to Warn (Count III).

II. Legal Standard

The admission of expert testimony in federal court is governed by Federal Rule of Evidence 702. In Daubert, the United States Supreme Court interpreted Rule 702 to require district courts to be certain that expert evidence based on scientific, technical or other specialized knowledge is "not only relevant, but reliable." Daubert, 509 U.S. at 589. The district court must make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 592-93.

The Eighth Circuit Court of Appeals has stated that proposed expert testimony must meet three criteria to be admissible under Rule 702. "First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy." Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001). "Second, the proposed witness must be qualified to assist the finder of fact." Id. (citation omitted). "Third, the proposed evidence must be reliable or trustworthy in an

evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires." Id. (internal quotation marks omitted). To meet the third requirement, the testimony must be "based on sufficient facts or data" and be "the product of reliable principles and methods," and the expert must have "reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d). "Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony[,]" Weisgram v. Marley Co., 169 F.3d 514, 523 (8th Cir. 1999), and "favors admissibility if the testimony will assist the trier of fact." Clark ex rel. Clark v. Heidrick, 150 F.3d 912, 915 (8th Cir. 1998). Doubt regarding "whether an expert's testimony will be useful should generally be resolved in favor of admissibility." Id. (citation and internal quotation omitted).

Under Rule 702, the trial court has gatekeeping responsibility to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999) (citing Daubert, 509 U.S. at 597). "When making the reliability and relevancy determinations, a district court may consider: (1) whether the theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review or publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operation; and (4) whether the theory or technique is generally accepted in the scientific community." Russell v. Whirlpool Corp., 702 F.3d 450, 457 (8th Cir. 2012) (citing Daubert, 509 U.S. at 593-94). "This evidentiary inquiry is meant to be flexible and fact specific, and a court should use, adapt, or reject Daubert factors as the particular case demands." Unrein v. Timesavers, Inc., 394 F.3d 1008, 1011 (8th Cir. 2005). "There is no single requirement for admissibility as long as the proffer indicates that the expert evidence is reliable and relevant." Id.

As a general rule "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination." Nebraska Plastics, Inc. v. Holland Colors Am., Inc., 408 F.3d 410, 416 (8th Cir. 2005) (quoted case omitted). However, "if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury, it must be excluded." Id. (quoted case omitted). An expert opinion is fundamentally unsupported when it "fails to consider the relevant facts of the case." Id.

III. Discussion

A. Abbott's Motion to Exclude Expert Witness Jack Land, M.D.

Abbott moves to exclude the testimony and evidence from plaintiff B.F.'s treating pediatrician, Jack Land, M.D. Abbott states that although Dr. Land treated B.F. for approximately seven years, from shortly after birth in September 2005 until October 2012, he treated him for routine pediatric conditions, and not specifically for spina bifida. Abbott says that because Dr. Land never treated B.F. for his spina bifida or the other conditions resulting therefrom that are the basis of this lawsuit, he should be barred from testifying. Alternatively, if Dr. Land were deemed qualified to testify, Abbott states he should not be permitted to give any testimony regarding B.F.'s future prognosis, testify that B.F. has strabismus (misalignment of the eyes) and that it resulted from his spina bifida, or testify that B.F. has hearing loss resulting from his spina bifida.

Plaintiffs respond that Dr. Land was B.F.'s treating pediatrician from birth to age seven, and his testimony is relevant, reliable, and will assist the jury. Plaintiffs state they designated Dr. Land to testify as a pediatric expert, particularly as B.F.'s pediatrician. The scope of his testimony is describing conditions that he has medical knowledge of and experience with as a

practicing pediatrician. Plaintiffs state that they have not designated Dr. Land as an expert to give detailed opinions on spina bifida and its causal link to Depakote. They also recognize that Dr. Land has not performed the particular specialized surgeries or other specialized treatments to address B.F.'s spina bifida and other conditions. But, Dr. Land has treated B.F. as his pediatrician and has treated and managed his spina bifida. "The fact is that Dr. Land is qualified and positioned as [B.F.'s] medical provider to explain to the jury [B.F.'s] medical conditions and treatments in relation to spina bifida." (Pl. Resp. at 8.)

1. The evidence would assist the jury

The Court finds that B.F.'s treating pediatrician's expert testimony regarding his treatment of B.F.'s spina bifida and other conditions would assist the jury in determining an ultimate issue of fact in this case. As B.F.'s pediatrician, Dr. Land was responsible for managing and coordinating B.F.'s overall care. Dr. Land's proposed testimony is therefore relevant.

2. Dr. Land is qualified to assist the jury

Abbott does not challenge Dr. Land's qualifications as an expert in the field of pediatrics. Dr. Land is a board certified pediatrician and a licensed medical doctor in the states of Missouri and Mississippi. Dr. Land founded and operated his own pediatric practice, Crystal City Pediatrics from 1990 to 2012. Prior to this practice, he was a pediatrician in the Air Force for eleven years. His pediatric experience includes the care of several patients with spina bifida. The Court finds Dr. Land is qualified to testify as an expert in pediatrics.

3. Reliability and Trustworthiness of the Proposed Evidence

Dr. Land intends to testify regarding the conditions of B.F. that relate to his spina bifida and conditions and treatments that subsequently occurred as a result of his spina bifida, including (1) hydrocephalus; (2) Chiari Type II malformation; (3) club feet deformity; (4) bilateral hip

dislocations; (5) tethering of spinal cord; (6) sensorineural hearing loss in the right ear; and (7) neurogenic bowel and bladder leading to incontinence of feces and urine. The facts and data considered in forming his opinions are based on his treatment of B.F. as his pediatrician and the medical records of B.F. up to the present.

Abbott specifically seeks to exclude any testimony regarding (1) whether B.F. may develop future medical needs, in particular, whether he will need to have his hydrocephalus shunt revised in the future; whether he may need another surgery for a tethered cord; whether he may need a derotational osteotomy; or whether he might develop scoliosis in the future; (2) whether B.F.'s strabismus resulted from his spina bifida; and (3) whether B.F.'s hearing loss resulted from his spina bifida. In each of these examples, Abbott thoroughly questioned Dr. Land at deposition regarding his opinions of B.F.'s medical condition and future medical needs.

With respect to the following future medical needs, it is clear that Dr. Land either does not intend to offer an expert opinion or he cannot offer an expert opinion within a reasonable degree of medical certainty: (1) whether B.F. may need another surgery for tethered cord; (2) whether B.F. may need a derotational osteotomy; and (3) whether B.F. might develop scoliosis. Taking each condition in turn, as to whether B.F. will need additional surgeries for spinal cord de-tethering, Dr. Land stated he did not intend to testify as to whether B.F. will need these additional surgery. (Dr. Land Dep. at 72.) With respect to B.F.'s hips and a possible derotational osteotomy surgery, Dr. Land testified that B.F.'s condition is "not currently felt to be surgically . . . appropriate for the hips, and that they're stable. . . . I can't tell what's going to happen long-term with that. . . . I can't say that's something he will or may not do in the future." (Id. at 62.) Finally, with respect to scoliosis, Dr. Land testified that he cannot state with a reasonable degree of medical certainty that B.F. will develop scoliosis. (Id. at 74.) Based on Dr.

Land's deposition testimony, with respect to these potential future medical needs, the Court finds that Dr. Land does not intend to offer an opinion, or his opinions are not scientifically valid as applied to the facts of this case. See Daubert, 509 U.S. at 590 (expert testimony must be based on "more than subjective belief or unsupported speculation"). Therefore, these three opinions will not assist the jury, and will be excluded.

With respect to whether B.F. will need his shunt revised in the future, Dr. Land testified that within a reasonable degree of medical certainty, B.F. will need to have his shunt revised. (Dr. Land Dep. at 70.) Dr. Land states that B.F. has more than a 50 percent chance of requiring a shunt revision, because statistically speaking patients with hydrocephalous shunts require revision. (Id.) The Court will allow this testimony as it finds Dr. Land is qualified to testify as to these facts and opinions. Any objection by Abbott to this testimony can be addressed by its expert witness or on cross examination of Dr. Land.

Abbott also seeks to exclude any testimony from Dr. Land that B.F.'s strabismus resulted from his spina bifida. When questioned regarding B.F.'s strabismus Dr. Land testified B.F. had recently been diagnosed with strabismus, but Dr. Land had not diagnosed this condition and he did not know which doctor had diagnosed the condition. (Id. at 74.) Dr. Land stated that he was not an expert in strabismus. (Id. at 50.) Dr. Land did not know whether B.F.'s reported headaches were related to the strabismus, and he testified that he is not offering a medical opinion as to whether the strabismus is causing B.F. any problems. (Id. at 75.) His knowledge regarding B.F.'s strabismus came entirely from interviewing Mrs. Forbes approximately a month before his deposition, and more than two years after he had stopped treating B.F. Dr. Land was not questioned regarding whether he believes B.F.'s strabismus resulted from his spina bifida. To the extent Dr. Land might seek to testify that B.F.'s strabismus results from spina bifida, the

Court will exclude this testimony as Dr. Land is not qualified to testify as to the cause of B.F.'s strabismus, a condition of which he was unaware, did not diagnose, and which presented more than two years after he stopped treating B.F.

Finally, Abbott seeks to exclude any testimony from Dr. Land that B.F.'s hearing loss results from spina bifida. Dr. Land testified as follows:

> Q: With respect to hearing loss in the right ear, is it your opinion that that's related to B.F.'s spina bifida?
>
> A: I think that's a real possibility.
>
> Q: What's that based on?
>
> A: There's an article that I found which is a woman's doctoral dissertation through the University of South Florida that looked at association with unilateral sensorineural hearing loss and placement of VP shunt for hydrocephalous.
>
> And since the hydrocephalous was a result of the Chiari, which is a result of the general spina bifida problem, it's my opinion that you can make a case that it is related to that.
>
> Q: When did B.F. first begin experiencing hearing loss?
>
> A. I think it was documented recently, but I don't know how long that's been going on.
>
> . . .
>
> Q: Do you know anything about the methodologies used to form the conclusions in that [doctoral dissertation through the University of South Florida]?
>
> A: I think it was just a statistical study.
>
> Q: Okay. Was this study published in a journal?
>
> A: No. I just found it as a doctoral thesis.
>
> Q: How did you find it?
>
> A: Google search or .gov search.

Q: You've not seen any publications in any medical journals; is that right?

A: I have not.

(Dr. Land Dep. at 65, 76-77).

Dr. Land did not diagnose B.F. as suffering from hearing loss nor has he conducted any examination of B.F.'s hearing loss. B.F. developed the hearing loss after Dr. Land had stopped treating him. Dr. Land's knowledge of B.F.'s hearing loss was through an interview with Mrs. Forbes shortly before his deposition. When asked whether the hearing loss was caused by B.F.'s spina bifida, Dr. Land stated "that's a real possibility." (Id. at 65.) Dr. Land's conclusion was based on his Google or .gov Internet search that pulled up an unpublished doctoral dissertation of an unidentified student from the University of South Florida. The Court finds that Dr. Land's testimony regarding the cause of B.F.'s hearing loss is not scientifically valid because it is based on an unidentified student's doctoral thesis that is untested, not subjected to peer review or publication, and there is no evidence it has been "generally accepted" in the medical community. Daubert, 509 U.S at 592-94. The Court will exclude any testimony of Dr. Land regarding the cause of B.F.'s hearing loss.

For the foregoing reasons, the Court will grant in part and deny in part Abbott's motion to exclude or limit the testimony of Dr. Jack Land. Dr. Land will not be permitted to: (1) give any testimony regarding whether B.F. will need another surgery for a tethered cord; will need a derotational osteotomy; or will develop scoliosis; (2) testify that B.F. has strabismus and that it resulted from his spina bifida; or (3) testify that B.F. has hearing loss and that it resulted from his spina bifida.

B. Abbott's Motion to Exclude Certain Opinion Testimony of Godfrey P. Oakley, Jr., M.D.

Abbott also seeks to exclude certain testimony of plaintiffs' expert Godfrey P. Oakley, Jr., M.D. Dr. Oakley is board certified in pediatrics, preventative medicine, and genetics. He has worked for the Centers of Disease Control and Prevention, focusing on using epidemiology to seek causes of birth defects and to prevent birth defects. Plaintiffs have designated Dr. Oakley as an expert to testify that (1) valproic acid (Depakote) taken early in pregnancy by Mrs. Forbes caused B.F. to be born with spina bifida, and (2) it was possible and reasonable for Abbott to have established as early as when valproic acid was first marketed in the United States a registry of exposed pregnancies.[1]

Abbott's motion seeks to exclude Dr. Oakley's second opinion, that it was reasonable for Abbott to have established a pregnancy registry. Abbott states that a pregnancy registry would have revealed nothing about the risk of spina bifida that was not both generally known and included in the Depakote label since 1985. That is, assuming Dr. Oakley's proposed pregnancy registry had been undertaken by Abbott, the outcome of such registry would have revealed nothing more than that a woman taking Depakote early in her pregnancy has a 1 to 2 percent risk of having a child with spina bifida. This risk had been included on the Depakote label since 1985.

Plaintiffs contend that Dr. Oakley's testimony about the pregnancy registry is relevant "because it is simply evidence of additional information about Depakote's risk profile which should have been available to Abbott." (Pls.' Resp. at 5.) "It is by no means a stretch to connect

[1] As explained by plaintiffs, a "pregnancy registry" is a method of tracking the effects of a drug on pregnant women and children exposed to a particular substance *in utero*. Pregnancy registries involve contacting women who become pregnant while taking a particular drug and obtaining information about the pregnancy and resulting child.

the probability that the more information collected, or vice versa, lack of information collected, will bear upon the adequacy of the warning." (Id.)

The admissibility of Dr. Oakley's testimony regarding the pregnancy registry turns on the basic rule of relevancy, which is fact specific. The evidence "must be useful to the finder of fact in deciding the ultimate issue of fact." See Lauzon, 270 F.3d at 686. In our case, plaintiffs claim that Abbott failed to warn of the risk of birth defects associated with Depakote. The birth defect at issue is spina bifida. At deposition, Dr. Oakley testified that the risk of spina bifida with Depakote exposure is 1 to 2 percent, and that this risk percentage is the same as he and other doctors had calculated in 1982.

> Q: As we're sitting here today 33 years later, the recognized absolute risk of spina bifida with valproic acid [Depakote] is 1 to 2 percent; true?
>
> A: That's correct.

(Dr. Oakley Dep. at 34.)

> Q: As of today . . . 2015 . . . your professional opinion is that the absolute risk of spina bifida with Depakote is 1 to 2 percent, true?
>
> A: That's true.[2]
>
> . . .
>
> Q: And so if those studies had been performed by Dr. McMann and Dr. Feinstein, we would have known the same thing about the absolute risk of spina bifida that we know today, true?
>
> . . .
>
> A: True.[3]

[2] In his errata sheet, Dr. Oakley clarifies this answer by stating: "That's true for the point estimate, but there is a confidence interval around that estimate." (Doc. 68-10.)

[3] Again in his errata sheet, Dr. Oakley clarifies this answer by stating: "True, but there would be a confidence interval around that point estimate." (Doc. 68-10.)

(Id. at 38.)

> Q: If Abbott had started a [pregnancy] registry in the 1980s or early 1990s based upon what we know today, would that registry likely have confirmed the 1 to 2 percent absolute risk of spina bifida?
>
> A: I believe that to be true.[4]
>
> . . .
>
> Q: All right. So that's what I was getting at. If Abbott had started a registry in the early 1980s or 1990s, that register, as far as you're concerned, would have given the same result in terms of the absolute risk of spina bifida from Depakote as what was known in 1982, true?
>
> A: True.[5]

(Id. at 117-18.)

Since 1985, Depakote's label has warned of the 1 to 2 percent absolute risk of spina bifida. According to Dr. Oakley, this absolute risk of spina bifida is still accurate today. If Abbott had initiated a pregnancy registry in the 1980s, as suggested by Dr. Oakley, it would have generated the same data that Abbott has included in its warning label since 1985. The registry would have simply confirmed the absolute risk of spina bifida that was already known and

[4] In his errata sheet, Dr. Oakley changes this answer for clarification purposes, stating: "I believe that to be true but it could have been higher or lower." (Doc. 68-10). Dr. Oakley's clarification changes his testimony without providing the basis on which it relies. His revised testimony is entirely speculative, and does not quantify the extent to which the absolute risk "could have been higher or lower." The Court finds this change to Dr. Oakley's testimony fundamentally unsupported, and the Court cannot find the testimony reliable or trustworthy in an evidentiary sense.

[5] Again in his errata sheet, Dr. Oakley changes this answer for clarification purposes, stating: "True, but it could have been higher or lower." (Doc. 68-10). The Court does not find this answer to be clarification of his original answer "True," but a substantive change to his testimony. This change does not provide the basis on which it relies, and is entirely speculative. Dr. Oakley does not quantify the extent to which the risk "could have been higher or lower." The Court finds this change to Dr. Oakley's testimony fundamentally unsupported, and the Court cannot find the testimony reliable or trustworthy in an evidentiary sense.

disclosed. The fact that Abbott could have undertaken a registry back in the 1980s, then, is not relevant in determining the adequacy of the spina bifida warning on the Depakote label when Mrs. Forbes was taking the medication. If Abbott had initiated a pregnancy registry, the label would have warned of a 1 to 2 percent risk of having a child with spina bifida; without the registry, the label already warned of a 1 to 2 percent risk of having a child with of spina bifida.

The pregnancy registry suggested by Dr. Oakley would not have given Mrs. Forbes or her prescribing physician any more information than Abbott had already provided on its label regarding the risk to Mrs. Forbes of having a baby with spina bifida. The Court finds that discussing Abbott's failure to create such a registry would serve only to prejudice Abbott. Because Dr. Oakley cannot testify that a pregnancy registry would have altered the spina bifida warning on Depakote's label, the Court finds that Dr. Oakley's expert testimony that it was possible and reasonable for Abbott to have established such a registry would not assist the jury in determining any ultimate issue of fact.

IV. Conclusion

For the foregoing reasons, Abbott's Daubert motion to exclude or limit the testimony of Jack Land, M.D. should be granted in part and denied in part. Abbott's Daubert motion to exclude certain opinion testimony of Godfrey P. Oakley, Jr., M.D. should be granted.

Accordingly,

IT IS HEREBY ORDERED that defendant Abbott Laboratories Inc.'s motion to exclude or limit the testimony of Jack Land, M.D. is **GRANTED in part** and **DENIED in part**. [Doc. 57] The motion is **GRANTED** to the extent that Dr. Land will not be permitted to: (1) give any testimony regarding whether B.F. will need another surgery for a tethered cord; will need a derotational osteotomy; or will develop scoliosis; (2) testify that B.F. has strabismus and

that it resulted from his spina bifida; or (3) testify that B.F. has hearing loss and that it resulted from his spina bifida. The motion is **DENIED** in all other respects.

IT IS FURTHER ORDERED that defendant Abbott Laboratories Inc.'s motion to exclude certain opinion testimony of Godfrey P. Oakley, Jr., M.D. is **GRANTED**. [Doc. 59]

IT IS FURTHER ORDERED that defendant Abbott Laboratories Inc.'s motion for oral argument is **DENIED as moot**. [Doc. 66]

CHARLES A. SHAW
UNITED STATES DISTRICT JUDGE

Dated this 6th day of May, 2016.